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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,256	06/28/2006	John Kim	00518-105029US1	3316
65989 7590 10/07/2010 KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003				
EXAMINER SHAHNAN SHAH, KHATOOL S				
ART UNIT 1645		PAPER NUMBER		
NOTIFICATION DATE 10/07/2010		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

# Office Action Summary

## Application No.

10/562,256

## Applicant(s)

KIM ET AL.

## Examiner

Khatol S. Shahnan-Shah

## Art Unit

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 16-32 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 21-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13, 16-18 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**RESPONSE TO AMENDMENT**

1. The amendment filed 7/7/2010 has been entered into the record. Claims 1-10 and 14-15 have been cancelled. New claims 16-32 have been added. Claim 11 has been amended.

***Status of Claims***

2. Claims 11-13 and 16-32 are pending.

***Election/Restrictions***

3. Applicants have submitted new claims 16-32 in the amendment filed 7/7/2010. Claims 19 and 21-32 are drawn to non-elected species, since on election of 12/02/2008 for election of species applicants have elected *Streptococcus* group B. Therefore claims 19 and 21-32 are withdrawn from examination. Claims 11-13, 16-18 and 20 are under examination.

***Rejections Withdrawn***

4. Rejection of claims 11-13 under 35 U.S.C. 102 (b) made in paragraph 8 of the office action mailed 3/20/2009 is withdrawn in view of amendment filed 7/7/2010.
5. Rejection of claims 11-13 under 35 U.S.C. 102 (b) made in paragraph 9 of the office action mailed 3/20/2009 is withdrawn in view of amendment filed 7/7/2010.
6. Rejection of claims 11-13 under 35 U.S.C. 102 (b) made in paragraph 10 of the office action mailed 3/20/2009 is withdrawn in view of amendment filed 7/7/2010.
7. Rejection of claims 11-13 under 35 U.S.C. 102 (b) made in paragraph 11 of the office action mailed 3/20/2009 is withdrawn in view of amendment filed 7/7/2010.
8. Rejection of claims 11-13 under 35 U.S.C. 102 (b) made in paragraph 12 of the office action mailed 1/7/2010 is withdrawn in view of amendment filed 7/7/2010.
9. Rejection of claims 11-13 under 35 U.S.C. 103 (a) made in paragraph 14 of the office action mailed 1/7/2010 is withdrawn in view of amendment filed 7/7/2010.

***New Rejections Based on Amendment***

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 11-13, 16-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michon *et al.* US 6,602,508 B2 in view of WO 99/15671 both IDS of record.

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B and wherein the Fragment C does not exist in the conjugate vaccine as part of a whole tetanus toxoid molecule, and wherein the conjugate vaccine does not increase a patient's anti-tetanus titer response.

Michon *et al.* teach multivalent GBS conjugate vaccines comprising the multivalent conjugates, wherein different types of GBS capsular polysaccharides including types I, II, III, IV and V are conjugated to a single protein, such as tetanus toxin (see abstract, claims, and columns 3 and 9). Michon *et al.* do not explicitly teach Fragment C, however, this deficiency has been overcome by the teachings of WO 99/15671

WO 99/15671. teach a polypeptide comprising tetanus toxin fragment C or a fragment thereof and conjugate vaccine wherein the Fragment C does not exist in the conjugate vaccine as part of a whole tetanus toxoid molecule, and wherein the conjugate vaccine does not increase a patient's anti-tetanus titer response (see abstract, claims and figures). WO 99/15671 teach a 50 kD polypeptide as fragment C generated by papain digestion from tetanus toxin (see page 3 detailed description of invention). WO 99/15671 teach vaccine which comprises fragment C and may include other antigens to provide a multivalent conjugate vaccine (see page 1).

It would have been *prima facie* obvious to one of skill in the art to combine the teachings of Michon et al. and WO 99/15671 to obtain the claimed invention. One of skill in the art would have been motivated by the teachings of WO 99/15671 to use fragment C and conjugate it to a capsular polysaccharide of *Streptococcus* group B because WO 99/15671. teach vaccine which comprises fragment C and may include other antigens to provide a multivalent conjugate vaccine (see column 3, lines 20-24).

### ***Conclusion***

12. No claims are allowed.
13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S. Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on Mon, Wed 12:30-6:30 pm, Thurs-Fri 12:30-4:30pm pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571)-2720832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call  
800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Khatol S Shahnan-Shah/

Examiner, Art Unit 1645

September 30, 2010

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1645